MIKROGEN DIAGNOSTIK

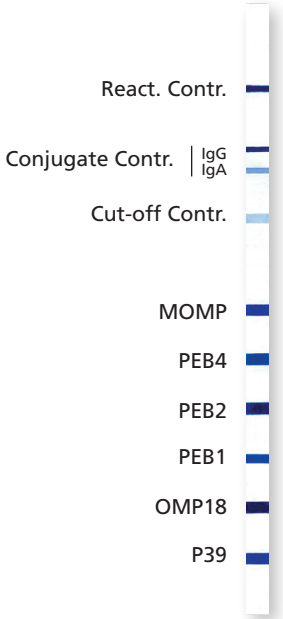
Increased sensitivity by use of P39

Automated Strip Interpretation recomScan

*recom*Line Campylobacter IgG
*recom*Line Campylobacter IgA

Strip-Immunoassay with antigens produced by recombinant techniques for the detection of IgG and IgA antibodies against *Campylobacter jejuni* and *Campylobacter coli*

The genus Campylobacter comprises gram-negative, spiral-shaped, microaerophilic, mesophilic to thermophilic bacteria with bipolar flagella. Human Campylobacter infections are mainly food associated intestinal infections with world-wide incidence. Contaminated and insufficient cooked foods or drinking water in tropical countries are the main sources of infection. The pathogen reservoir is mainly the intestinal tract of warm-blooded wild, domestic and pet animals. Intestinal Campylobacter infections are the second most frequent enteric bacterial infections reported in Germany after enteric Salmonelloses, whereas unreported cases not reflected in the statistics probably outnumber reported cases many times over.



Campylobacter jejuni is much more frequent, accounting for over 90% of cases as compared to Campylobacter coli at approx. 9%. Besides nearly asymptomatic (clinically inapparent) courses, infected persons suffer from painful gastrointestinal symptoms with sometimes bloody diarrhoea, fever, meningism and myalgias. In rare cases sequelae like postinfectious Reactive Arthritis or Guillain-Barré Syndrome may develop with onset a few weeks after the primary infection.

*recom*Line Campylobacter is a qualitative in-vitro test for the detection of IgG and IgA antibodies against immunodominant antigens of *Campylobacter jejuni* and *Campylobacter coli*. In cases of previous or persistent Campylobacter infection with primary diagnosis based on stool sample culturing, recomLine Campylobacter provides for identification of specific Campylobacter antibodies by means of separate lineups of different antigens produced by recombinant engineering for the purpose of clarifying postinfection complications.

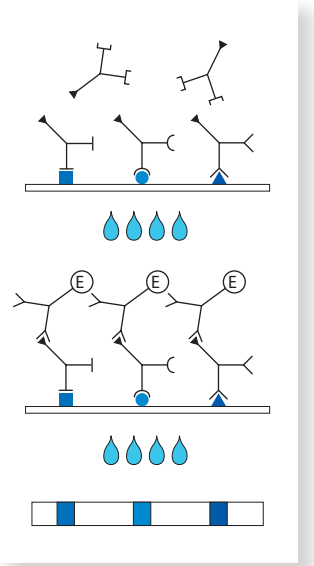
Product advantages

- Recombinant antigens
  - ➢ High sensitivity and specificity
  - ➢ Easy and clear interpretation due to easy to read bands
- Easy test procedure; automation possible
- Easy and objective strip interpretation and documentation with *recom*Scan software
- Test procedure and reagents identical in all MIKROGEN strip tests - reagents exchangeable
- Safe evaluation due to strip specific controls (cut-off and conjugate control)
- Separate detection of IgG and IgA antibodies possible
- CE label: The *recom*Line Campylobacter tests meet the high standard of the EC directive 98/79/EC on in vitro diagnostic medical devices

Related recombinant Campylobacter antigens

Description	Antigen	Molecular Weight [kDa]
Major outer membrane protein (porA)	MOMP	46
Cell-binding factor 2 (cbf2)	PEB4	31
Major antigenic peptide PEB2	PEB2	27
Major cell-binding factor (cbf1)	PEB1	28
Peptidoglycane associated lipoprotein	OMP18	18
Putative ATP/GTP binding protein	P39	39

Test Principle and Procedure



1st Incubation A test strip loaded with Campylobacter antigens is incubated with diluted serum or plasma in a dish for **1 hour**.

wash 3 times

2nd Incubation Peroxidase conjugated anti-human antibodies (IgG or IgA specific) are added. Incubate for **45 minutes**.

wash 3 times

Color reaction **5 - 10 minutes** after addition of the coloring solution, insoluble colored bands develop at the sites on the test strips occupied by antibodies.

Evaluation

Patient samples from different sources were tested to assess the performance capability of *recom*Line Campylobacter IgG/IgA. Additional data on the frequency of positive reactivity for the individual recombinant antigens are listed.

*recom*Line Campylobacter IgG	n	Frequencies of the recombinant antigens (%)						IgG-positive
		MOMP	PEB4	PEB2	PEB1	OMP18	P39	
*C. jejuni, C. coli positive stool culture**	250	5	21	3	6	53	69	**80%**
GBS samples with unclarified aetiology**	30	13	13	10	7	10	n.d.	**20%**
ReA samples with unclarified aetiology***	56	5	9	2	0	12	14	**30%**
Blood donors	160	2	3	1	1	6	8	**14%**

*recom*Line Campylobacter IgA	n	Frequencies of the recombinant antigens (%)						IgA-positive
		MOMP	PEB4	PEB2	PEB1	OMP18	P39	
*C. jejuni, C. coli positive stool culture**	250	2	2	0	1	18	26	**37%**
GBS samples with unclarified aetiology**	30	7	7	0	0	3	n.d.	**10%**
ReA samples with unclarified aetiology***	56	2	2	0	2	4	2	**7%**
Blood donors	160	1	1	0	1	1	1	**2,5%**

* Samples from patients with positive Campylobacter stool cultures (C. jejuni, C. coli). Blood samples were taken 0 to 40 days after the stool diagnostics, the beginning of the disease was unknown.

** Samples from patients with suspected Guillain-Barré-Syndrom (GBS) unclarified aetiology. No data on previous illnesses involving diarrhoea were known. (Testet with recomLine Campylobacter without P39)

*** Samples from patients with suspected Reactive Arthritis (ReA) unclarified aetiology. No data on previous illnesses involving diarrhoea were known.

Article-No

6272 ***recom*Line Campylobacter IgG**
Reagents for 20 determinations

6273 ***recom*Line Campylobacter IgA**
Reagents for 20 determinations

Storage

At +2°C - +8°C

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